The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Quality
10 West Street, Boston, MA 02111-1212
617-753-8000

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

RONALD PRESTON
SECRETARY

CHRISTINE C. FERGUSON
COMMISSIONER

TO: Commissioner Ferguson and Members of the Public Health Council

FROM: Paul Dreyer, Director
Division of Health Care Quality

DATE: February 24, 2004 (Issued February 17, 2003)

RE: Request for Final Promulgation of Amendments to the Hospital Licensure Regulations (105 CMR 130.000) Regarding the Designation of Primary Stroke Services

Over the past several months, the Department has been working with clinicians, hospitals, and advocates to develop standards for designating Primary Stroke Services in hospitals that are equipped to rapidly triage and treat patients presenting with symptoms of acute stroke. These standards for voluntary designation are based on the nationally recognized consensus position outlined in "Recommendations for the Establishment of Primary Stroke Centers," which appeared in JAMA, June 21, 2000, Vol.283, No.23, pages 3102-3109.

Background

Each year over 3500 Massachusetts citizens die from stroke. Stroke is the third leading cause of death in Massachusetts and a leading cause of disability. Stroke is a type of cardiovascular disease that affects the arteries leading to and within the brain. There are two major types of acute stroke. Acute hemorrhagic stroke occurs when a blood vessel, which carries oxygen and nutrients to the brain, ruptures and causes bleeding into or around the brain. Acute ischemic stroke occurs when a blood vessel to the brain is blocked by a clot. An estimated eighty percent of strokes are ischemic. Historically, no effective treatment has been available for acute ischemic stroke. Clinical trials have established thrombolytic therapy as an effective treatment if administered within limited time parameters. Based on these clinical trials, the Food and Drug Administration approved the use of tissue-type plasminogen activator, a thrombolytic agent also known

as t-PA, for patients with acute ischemic stroke if given within three hours of symptom onset. However, less than five percent of people with acute ischemic stroke receive thrombolytic agents within the recommended time frames. The American Heart Association and other clinical standard setting entities have recommended that Primary Stroke Services be established to ensure that clinically eligible patients are afforded the opportunity to receive this definitive care.

Proposed Amendments to the Hospital Licensure Regulations

With the goal of improving the care and outcomes of acute ischemic stroke patients, the Department drafted proposed amendments to the hospital licensure regulations to establish standards for Primary Stroke Services. Under the proposed amendments, a hospital providing licensed emergency services may apply for designation. The standards, as originally proposed, included the following hospital requirements:

1) creation of an Acute Stroke Team, with a physician director who has training and expertise in cerebrovascular disease,
2) development and implementation of written care protocols,
3) availability of the service 24 hours per day, seven days a week,
4) development and implementation of effective communication with Emergency Medical Service personnel in the pre-hospital setting during the transportation of a patient with symptoms of acute stroke,
5) rapid availability of neuroimaging and other imaging, electrocardiogram, laboratory and neurosurgical services,
6) continuing health professional education,
7) development and implementation of quality assessment and improvement programs, and
8) data collection, with submission of select data elements to a data center approved by the Department.

Public Hearing and Comment

The Department conducted a public hearing on December 29, 2003. Approximately 30 people attended the hearing. Four people presented oral testimony. The Department also accepted written comments on the proposed amendments through January 9, 2004. The comments and the Department's response are summarized in Attachment A. The Department has made the following revisions based on the public comments:

1) 105 CMR 130.1412: Added a requirement that the hospitals provide to the community information on prevention of stroke, recognition of stroke symptoms, and stroke treatment.

2) Deleted the definition of Data Center and revised 105 CMR 130.1410, deleting the specifics regarding data elements. The Department will define the data collection and submission requirements in its advisory bulletin.

3) Replaced the words ‘rapid’ and ‘rapidly’ with ‘prompt’ or ‘promptly’ throughout the document, except in the definitions of Acute Hemorrhagic Stroke, Acute Ischemic Stroke and Acute Stroke and clarified in 105 CMR 130.1405 that time to treatment under the hospital’s written care protocols must be consistent with time targets acceptable to the Department.

Recommendation:

Based on the above, the Department requests approval for final promulgation of the amendments as revised (see Attachment B) based on the public comments.